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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,488	08/25/2003	Kai-yu Tong	MCHK/131/US	2363
2543	7590	02/23/2006	EXAMINER	
ALIX YALE & RISTAS LLP 750 MAIN STREET SUITE 1400 HARTFORD, CT 06103			PATEL, JOY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/647,488	<b>Applicant(s)</b> TONG, KAI-YU	
	<b>Examiner</b> Joy P. Patel	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/17/04</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

✓

## **DETAILED ACTION**

### ***Oath/Declaration***

1. Neither copy of the oath is dated. Furthermore, in one copy, the applicant claims citizenship to China, while claiming citizenship to Hong Kong.

### ***Drawings***

The drawings are objected to because:

- a. Figure 1 discloses element 1. However, element 1 is not discussed in the specification.
- b. Figure 7 discloses element 105. However, element 105 is not discussed in the specification.
- c. Figure 23 discloses elements 158, 160-163. However, these elements were never discussed in the specifications.
- d. Figure 24 discloses element 165. However, element 165 is not discussed in the specification.
- e. Figure 25 discloses element 171. However, element 171 is not discussed in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

- f. On page 1, line 18, "core injured" should be changed to "cord injury".

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- g. On page 2, line 15, the word "choice" does not make much sense. It is suggested this word be replaced with another more appropriate word or phrase.
- h. On page 3, the sentence beginning with "According to..." is a run-on sentence.

Appropriate correction is required.

### ***Claim Objections***

- 3. Claim 1 is objected to because of the following informalities: Claim 1 claims an output comprising "a rise signal, a stimulation signal, and a fall signal..." However, from page 4 of the specification and from figure 4, it seems as though the applicant intended to mean "a stimulation signal, consisting of a rise portion, a stimulation portion, and a fall portion" as is indicated in these areas. For examination purposes, the claim will be interpreted as stated above due to lack of support for the way it is currently written. The examiner also notes that the applicant has disclosed "an output comprising a rise signal, a stimulation, and a fall signal..." but has failed to provide any supporting information regarding this statement.

### ***Claim Rejections - 35 USC § 112***

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4. Claim 6 recites the limitation "the stimulation file and log file" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Claim 2 only claims a stimulation file and does not claim a log file.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 2, 4, 5-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Haugland et al. (US 2003/0144710).
6. In regard to claim 2, see Haugland et al. (US 2003/0144710) figure 5. Here, Haugland discloses a sensor for detecting a movement event of a body part (the heel switch); See also Abstract, lines 1-3), an electrode for making electrical contact with an area of the body part (multipolar nerve stimulation electrode), and a controller (Power and stimulus control transmitter; See also Paragraphs 79 and 80). The "remote unit" is taken by the examiner to be the "programming unit with radio transmitter", which

sends data to the “power and stimulus control transmitter” (a part of the external patient worn housing). In paragraph 82, Haugland discloses, “the radio receiver is optional, but facilitates the programming of parameters into the device from the programming unit and makes it possible to have a wireless heel switch...” (See also paragraphs 81 and 83). The examiner therefore considers the radio receiver and power and stimulus control transmitter to be one external unit, which Haugland describes as being placed “On the surface of the skin over an implanted portion of the device...for transmitting power and control information to the implant...” (Paragraph 79). Furthermore, since the device is external to the implant site, it can be worn on the outside of the body as is disclosed by the incorporated reference to Liberson (See Fig. 1). The stimulation device (power and stimulus control stimulator) also stores stimulation data, as is disclosed by Haugland in paragraph 80. Here, Haugland discloses, “...it has been implemented with a microcontroller, that stores a program for communicating with the implant and that stores the parameters for the stimulation...The unit has inputs...for programming stimulation parameters into the unit. It further has a connector for downloading a new program into the unit.” (Paragraph 80; See also paragraphs 78 and 79). Here, the file that stores the stimulation information is considered by the examiner to be the “stimulation file”. Finally, the controller has inputs for receiving input data from the heel switch. This information is then analyzed and an appropriate stimulation signal is output (see Figure 8).

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7. In regard to claim 4, see Figure 14. From figure 14, elements 140, 146 and 147, one can observe the “rise portion”, “rise time”, “stimulation portion”, “stimulation time”, “fall portion”, and “fall time” of the stimulation pulses 146 and 147.
8. In regard to claim 5, Haugland discloses, “The purpose of the stimulator is to deliver electrical pulses to the contacts in the stimulation electrode” (Paragraph 72, lines 1-2). In paragraphs 86-90, Haugland discloses that the programming unit makes it possible to set specific parameters for the stimulation including: a threshold and maximum stimulation for each channel, a stimulation frequency for each channel, and the ramp-up time after the heel is lifted from the ground for each channel. Here, the triggering period is taken by the examiner to be the “ramp-up” and “ramp – down” (discussed in paragraph 90) times are considered to be the triggering period, the triggering criteria include sensing the movement of the heel off of the ground and the threshold for each of the stimulation channels. The triggering method is taken by the examiner to be the method wherein the “ramping-up” occurs when the heel is lifted off of the ground and the stimulation wave is generated for a predetermined time and then “ramps-down” and stops again (Again, see paragraphs 86-90).
9. In regard to claims 6 and 7, see rejection for claim 2 above. Furthermore, Haugland discloses that the “programming unit with radio transmitter”, which is used to set the stimulation parameters for the external device, is considered by the examiner to be the “remote unit” of claim 2 can be



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either a hand-held unit or a PC with a suitable program (See paragraph 85). It is well known in the art that PCs and hand-held units such as PDAs are capable of downloading and storing information. In this case, it would be downloading a "stimulation file" and a "log file" from the device into its database (which can be located on the hard drive of the computer). Furthermore, computers and PDAs both contain display screens which can display downloaded data, as is common in the art.

10. In regard to claim 9, see rejection for claim 2. Furthermore, See paragraph 85, here Haugland discloses that the "programming unit with radio transmitter" (the "remote control unit") "...can be either a hand-held dedicated unit, or a PC with a suitable program)" (Paragraph 85, line 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al. (US 2003/0144710) in view of Nelson et al. (US 5,586,557).
12. In regard to claims 1 and 10, see Haugland et al. (US 2003/0144710) figure 5. Here, Haugland discloses a sensor for detecting a movement

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event of a body part (the heel switch); See also Abstract, lines 1-3), an electrode for making electrical contact with an area of the body part (multipolar nerve stimulation electrode), and a controller (Power and stimulus control transmitter; See also Paragraphs 79 and 80) coupled to the sensor and electrode which receives sensory information regarding a movement event and generates an output signal accordingly (see paragraph 60 regarding the function of the heel switch). Furthermore, from figure 14, elements 140, 146 and 147, one can observe the "rise portion", "rise time", "stimulation portion", "stimulation time", "fall portion", and "fall time" of the stimulation pulses 146 and 147. However, Haugland, as discussed above, fails to teach that the number of movement events and the duration of use were recorded. Nelson, on the other hand, teaches a device for measuring a patient's walking performance by using a heel and toe switch to generate positional and time signals, which are sent to a computer to be processed. The computer then uses these signals to determine "...the duration of the walk and the number of steps taken over a preset distance" (See column 3, lines 15-17). This information is then analyzed to assess the ambulation performance of the patient's gait. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Haugland in view of the teachings of Nelson in order to create a stimulation device that would record the duration of use of the device, along with the number of movements in order to assess the ambulation performance of a patient's gait in order to

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test the effectiveness of the current treatment and to modify it accordingly.

In specific regard to claim 10, a heel switch is implemented.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al (US 2003/0144710) in view of Nelson et al. (US 5,586,557) in further view of Levine (US 6,594,523).
14. In regard to claim 3, Haugland in view of Nelson (as discussed above for claim 1) discloses a controller designed to measure a duration and the number of movement events during that duration, but fails to teach that the information is stored in a log file. Levine, on the other hand, teaches an external programmer for a pacemaker that creates a log file of all of the data collected during a session in the external programmer (Column 13, lines 36-58). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Haugland in view of Nelson, in further view of the teachings of Levine to have an external programmer that would store information regarding the duration and number of movement events into a log file so that it could be analyzed at a later time and adjustments could be made to the stimulation patterns accordingly.
15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haugland et al. (US 2003/0144710), in view of Nelson et al. (US 5,586,557), in further view of Sieracki et al. (US. 2004/0143302).

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16. In regard to claim 8, Haugland in view of Nelson, as discussed above, disclose an implantable stimulation system with an external "remote unit", comprised of a PC or hand held device used to program the external stimulator of the stimulation system. However, Haugland in view of Nelson, fails to teach that the database (in this instance, the computer's hard drive) includes patient information and a graphical user interface (GUI). Sieracki, on the other hand, discloses an implantable stimulator with an external controller, such as a PDA (see Fig. 1), that sends programs and rating information associated with the program to the server during a programming session, along with patient information so that the physician can compare the patient's responses to certain treatments and adjust the treatment appropriately based on information stored in the database (See abstract and paragraph 10). Sieracki also discloses that the external controller has a graphical user interface (GUI) to facilitate interaction with the clinician (See paragraph 41). Therefore, it would have been obvious for one of ordinary skill in the art to modify the device of Haugland in view of the teachings of Nelson in further view of the teachings of Sieracki, in order to provide a more effective treatment for the patient and to make the database easier to access by a physician. In regard to the Windows GUI, the Windows operating system is the most commonly used OS (operating system) on the market. Therefore, to use a Windows GUI would have been obvious to anyone of ordinary skill in the art.


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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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